JAN 2 1 2005

K042885

Ophthalmic Technologies Inc.
Special 510(k) Submission
OCT- Ophthalmoscope

510(k) Summary
September 30, 2004

(1) Submitter Information

Name: Ophthalmic Technologies Inc.

Address:

Ophthalmic Technologies Inc.
37 Kodiak Crescent, Unit 16
Downsview, Ontario, Canada M3J 3E5

Telephone number:

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Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: December 10, 2002

(2) Name of Device

Trade Name: OCT- Ophthalmoscope
Common Name: Ophthalmoscope using optical coherence tomography
Classification name: Ophthalmoscope, a-c powered, 886.1570

(3) Equivalent legally-marketed devices.

K012727, Optical Coherence Tomography Model 3000, Zeiss Ophthalmic Systems
K943956, Retina Tomograph and Flowmeter, Heidelberg Engineering

(4) Description

The OTI OCT Ophthalmoscope produces simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of

the eye fundus. In addition conventional longitudinal OCT images may also be collected.

The system uses a high power superluminescient diode operating at 850nm. The software uses a tabbed interface: the user can select any of the primary functional modules at any time by clicking on the tab for that function at the top of the screen. When there are several major components in a function, these are presented as tabs below the principal tab bar.

(5) Intended Use

The OTI OCT Ophthalmoscope is intended to offer simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of the eye fundus. In addition conventional longitudinal OCT images may also be collected.

(6) Performance Data

(a) Non-clinical tests

The OCT-Ophthalmoscope has had accuracy tests, optical emissions analyses, electrical safety tests, and software validation tests.

(b) Clinical tests

Not required.

(c) Conclusions

The OCT-Ophthalmoscope is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2007

Ophthalmic Technologies, Inc.
c/o George Myers, Sc.D.
Medsys, Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K042885
Trade/Device Name: OCT-Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: OBO
Dated: October 17, 2004
Received: November 18, 2004

Dear Dr. Myers:

This letter updates our substantially equivalent letter of January 21, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Gwendolyn Keyes PhD

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: OCT- Ophthalmoscope

Indications for Use:

The OTI OCT Ophthalmoscope is intended to offer simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of the eye fundus. It is indicated in situations where these images are required for diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____

_____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K042885